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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,857	08/08/2001	Donogh P. O'Brien	P0378P3C6	3539

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EXAMINER

GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 10/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary		Application No. 09/924857	Applicant(s) O BRIEN	
		Examiner BE CAMPBELL	Art Unit 644	

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 8/8/01

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 18 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 18 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on 8/6/01 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

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DETAILED ACTION

1. Applicant's amendment, filed 8/8/01 (Paper No. 2), has been entered.
Claim 1-17 have been canceled.
Claim 18 has been added.

2. The filing date of the instant claims is deemed to be the filing date of the priority application USSN 07/209,665, filed 6/21/88, as the previous priority applications USSNs 06/926,977, filed 11/4/86 and 07/110,255, filed 10/20/87 do not support the claimed limitations of the instant application, encompassing methods of inhibiting coagulation with LACI.

If applicant disagrees, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the earlier priority applications. Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. § 112, first paragraph.

3. If applicant desires priority under 35 U.S.C. 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Applicant should restrict the title to the claimed invention.

5. The Abstract of the Disclosure is objected to because it does not adequately describe the claimed invention. Correction is required. See MPEP 608.01(b).

6. Formal drawings and photographs have been submitted which comply with 37 CFR 1.84

7. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

Trademarks should be capitalized or accompanied by the TM or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate corrections are required

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8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

10. Claim 18 is rejected under 35 U.S.C. § 102(e) as being anticipated by Broze et al. (U.S. Patent No. 5,106,833) (see entire document).

Broze et al. teach a method of inhibiting Factor Xa production of Factor VIIa/TF (tissue factor) enzymatic complex formation in a mammal with the coagulation inhibitor LACI (see Background of the Invention, Summary of the Invention, Detailed Description of the Invention, Claims). Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. Given the referenced methods of inhibiting Factor Xa production or Factor VIIa/TF enzymatic complex formation in a mammal with the coagulation inhibitor LACI (e.g. see Claims), as well as the disclosure of the controlling the coagulation cascade in the Background of the Invention, one of ordinary skill in the art would have immediately envisaged the treatment of coagulation disorder as the target of the claimed patented methods at the time the invention was made.

It is noted that Broze et al. focuses on fragments of LACI for inhibiting Factor Xa or Factor VIIa/TF complex (e.g. see Brief Description of the Invention in column 2 and Detailed Description of the Invention in columns 2-6 and Claims).

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However, the instant claims do not distinguish the claimed LACI comprising LACI and the prior art teachings of LACI, including the inhibitory fragments of LACI.

Further, it is noted that Broze et al. claims priority to both USSN 07/077,366 and 07/123,753 (see column 1, lines 5-10).

Broze et al. further incorporates by reference to the disclosure of USSN 07/077,366 (see column 1, lines 33-53). The disclosure of USSN 07/077,366 further provides for the tissue factor inhibitor (later referred to as LACI) and its therapeutic use as a coagulation inhibitor and anti-thrombotic agent (See entire disclosure, including Brief Description of the Invention). In addition, the disclosure of USSN 07/077,366 provides for methods of inhibiting factor Xa production or Factor VIIa/TF enzymatic complex formation with intact tissue factor inhibitor (i.e. LACI) (see claims 5-6). A courtesy copy of USSN 07/077,366 is provided as an attachment for applicant's convenience.

It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001).

11. Claims 18 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Broze et al. (U.S. Patent No. 5,106,833) further in view of Broze et al. (PNAS 84: 1886-1890, 1987) (1449; #23) AND/OR Broze et al. (Blood 71: 335-343, 1988) (1449; #24).

Broze et al. teach a method of inhibiting Factor Xa production of Factor VIIa/TF enzymatic complex formation in a mammal with the coagulation inhibitor LACI (see Background of the Invention, Summary of the Invention, Detailed Description of the Invention, Claims). Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. Given the referenced methods of inhibiting Factor Xa production of Factor VIIa/TF enzymatic complex formation in a mammal with the coagulation inhibitor LACI (e.g. see Claims), including the Background of the Invention disclosure of the coagulation cascade, one of ordinary skill in the art would have immediately envisaged the treatment of coagulation disorder as the target of the claimed patented methods at the time the invention was made.

As pointed out above, further, it is noted that Broze et al. claims priority to both USSN 07/077,366 and 07/123,753 (see column 1, lines 5-10).

Broze et al. further incorporates by reference to the disclosure of USSN 07/077,366 (see column 1, lines 33-53). The disclosure of USSN 07/077,366 further provides for the tissue factor inhibitor (later referred to as LACI) and its therapeutic use as a coagulation inhibitor and anti-thrombotic agent (See entire disclosure, including Brief Description of the Invention). A courtesy copy of USSN 07/077,366 is provided as an attachment for applicant's convenience.

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As pointed out above, the instant claims do not distinguish the claimed LACI comprising LACI and the prior art teachings of LACI, including the inhibitory fragments of LACI.

In addition, the disclosure of USSN 07/077,366 provides for methods of inhibiting factor Xa production or Factor VIIa/TF enzymatic complex formation with intact tissue factor inhibitor (i.e. LACI) (see claims 5-6).

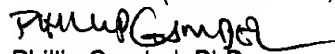
Similar to the Broze et al. Patent, Broze et al. (PNAS) teach the isolation of the tissue factor inhibitor, now known as LACI (See entire document). In addition to the teachings of the inhibition of factor VIIa-tissue factor, Broze et al. (PNAS) also teach that factor VII-tissue factor pathway of coagulation is involved in several pathological conditions associated with disordered coagulation and thrombosis (see first paragraph of Introduction).

Broze et al. (Blood) teach LACI inhibits factors VIIa-tissue factor and plays an important role in the in vivo coagulation and be useful in treatment (See entire document, including Abstract on page 335; also see the last paragraph of the Discussion on page 342).

Given the referenced methods of inhibiting Factor Xa production of Factor VIIa/TF (tissue factor) enzymatic complex formation in a mammal with the coagulation inhibitor LACI, one of ordinary skill in art at the time the invention was made would have been motivated to employ LACI in therapeutic regimens associated with pathological conditions associated with disordered coagulation and thrombosis. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 872-9306.


Phillip Gambel, PhD.

Primary Examiner
Technology Center 1600
September 29, 2003